Energy Automation Systems, Inc. v. Xcentric Ventures, LLC et al Doc. 25 Att. 8

LEXSEE 2006 U.S. DIST. LEXIS 65702

**UNITED STATES OF AMERICA and STATES OF CALIFORNIA and FLORIDA ex rel. ROBERT A. FRY, Plaintiff-Relator v. GUIDANT CORPORATION, its predecessor Cardiac Pacemakers, Inc., a division of Eli Lilly and Company, and unknown entities and individuals, Defendants**

**Case No. 3:03-0842**

**UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE, NASHVILLE DIVISION**

***2006 U.S. Dist. LEXIS 65702***

**September 13, 2006, Decided**
**September 13, 2006, Filed**

**PRIOR HISTORY:** *United States ex rel. Fry v. Guidant Corp., 2006 U.S. Dist. LEXIS 29862 (M.D. Tenn., Apr. 25, 2006)*

**COUNSEL:** [*1] For Robert A. Fry, Plaintiff: Ernest Clayton Yates, Yates & Mancini, LLC, Fort Pierce, FL, US; John S. Hughes, Wallace and Graham, P. A., Salisbury, NC, US; Mary Ann Parker, Parker & Crofford, Nashville, TN; Mona Lisa Wallace, Wallace and Graham, P.A., Salisbury, NC, US; Richard A. Fisher, Richard Fisher Law Office, Cleveland, TN; Stephen C. Crofford, Parker & Crofford, Nashville, TN; Suzanne B. Giorgi, Attorney General's Office, Bureau of Medi-Cal Fraud & Elder, Abuse, Sacramento, CA; Theodore J. Leopold, Ricci Leopold, Palm Beach Gardens, FL, US.

For USA, ex rel., Plaintiff: Michael L. Roden, Office of the United States Attorney, Nashville, TN; Suzanne B. Giorgi, Attorney General's Office, Bureau of Medi-Cal Fraud & Elder, Abuse, Sacramento, CA.

For Guidant Corporation, Defendant: Evangeline G. Paschal, Akin, Gump, Strauss, Hauer & Feld, LLP, Washington, DC; John M. Dowd, Akin, Gump, Strauss, Hauer & Feld, LLP, Washington, DC; Jennifer L. Weaver, Waller, Lansden, Dortch & Davis, Nashville, TN.

For Guidant Sales Corporation, Defendant: Jennifer L. Weaver, Waller, Lansden, Dortch & Davis, Nashville, TN.

For State of Tennessee, Movant: Michael Kevin Bassham, Tennessee [*2] Attorney General's Office, Nashville, TN; Peter M. Coughlan, Tennessee Attorney General's Office, Nashville, TN; Jeremy E. Pyper, Tennessee Attorney General's Office, Nashville, TN.

**JUDGES:** ALETA A. TRAUGER, United States District Judge.

**OPINION BY:** ALETA A. TRAUGER

**OPINION:**

**MEMORANDUM**

This matter comes before the court on a Motion to Dismiss filed by defendant Guidant Corporation (Docket No. 96), to which the relator has responded (Docket No. 100), and the defendant has replied (Docket No. 104). In addition, this memorandum will consider the Motion to Authorize Disclosure filed by the relator (Docket No. 106), the Motion to Strike the United States' Notice of Pending Reconsideration filed by defendant Guidant Corporation (Docket No. 108), to which the United States has responded (Docket No. 112), the Motion to Strike Documents Filed Under Seal filed by defendant Guidant Corporation (Docket No. 116), to which the United States has responded (Docket No. 118), and the Motion to Strike the Relator's Omnibus Brief filed by Defendant Guidant Corporation (Docket No. 119), to which the relator has responded (Docket No. 120). For the reasons

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discussed herein, the defendant's Motion to Dismiss [*3] will be denied; the defendant's Motion to Strike the United States' Notice of Pending Reconsideration, the defendant's Motion to Strike the United States' Documents Filed Under Seal, and the defendant's Motion to Strike the Relator's Omnibus Brief will each be denied; and the relator's Motion to Authorize Disclosure will be granted.

**FACTUAL BACKGROUND AND PROCEDURAL HISTORY**

Defendant Guidant Corporation ("Guidant") manufactures and sells implant medical devices ("IMDs"), such as defibrillators and pacemakers, to doctors and hospitals throughout the United States. n1 Relator Robert A. Fry was employed as a salesman for Guidant, covering the states of Tennessee and Kentucky, from April 1981 until March 1997. Mr. Fry alleges that, during those years, Guidant engaged in a fraudulent scheme to defraud hospitals by concealing the existence of warranty rebates and "upgrade" credits for replacement IMDs. In so doing, Mr. Fry alleges that Guidant caused hospitals to submit Medicare claims that overstated the actual replacement costs for those devices.

n1 Unless otherwise noted, the facts have been drawn from the relator's Second Amended Complaint (Docket No. 94).

[*4]

According to Relator Fry, the scheme operated as follows. Guidant marketed its IMDs, through salesman such as Fry, directly to the doctors who perform the implant procedures for the devices. Although hospitals ultimately purchased the devices from Guidant, the doctors who performed the procedures were able to dictate to the hospitals which brand of IMD would be used, as a function of market forces between doctors and hospitals. Salesmen such as Mr. Fry told those doctors that Guidant's IMDs came with warranty rebates and "upgrade" credits, as sales incentives relating to the out-of-pocket costs to their patients. However, Guidant concealed the availability of the rebates and credits to the hospitals themselves, charging the hospitals for the full costs of IMDs where rebates and credits applied. These costs were, in many cases, ultimately shifted to the federal government through the Medicare and Medicaid programs. n2

n2 Mr. Fry alleges that he and other Guidant sales agents were instructed at a training session that 78% of pacemakers are implanted in patients who are on Medicare.

[*5]

Relator Fry alleges that it was Guidant's policy to actively conceal the warranties for IMD devices from hospital personnel. For instance, during the implant procedures, Mr. Fry alleges that it was the practice of Guidant salesmen to open and remove the IMD from its sealed container and dispose of the container, with the IMD's written warranty, in the operating room's trash can. During a period of time at St. Thomas Hospital, located in Nashville, Tennessee, Guidant salesmen were barred from the operating room during the implant procedures. In order to keep the warranties from hospital personnel, Guidant agents instructed the clinical technician or pacing nurse to deliver the warranty to the doctor's office, or place the warranty in the patient booklet that was taken home by the patient.

Without access to the written warranty, the hospital personnel responsible for paying Guidant's bills, and for requesting reimbursement from Medicare and Medicaid, had no knowledge of the availability of warranty credits. Almost uniformly, the hospitals failed to take advantage of the warranty credits and passed the cost on to Medicare and Medicaid by submitting the higher costs of replacement in [*6] their Cost Reports. Thus, according to Mr. Fry, Guidant designed a system where hospitals virtually never utilized those credits and, in cases where the patient was covered by Medicare and Medicaid, the cost was ultimately borne by the federal government. In addition, Guidant developed and pitched to doctors non-warranty replacement rebates for IMDs, such as a "competitive replacement program" and a "Cardiassure" program, while ensuring that the rebates discussed with the doctors were never received by the hospitals' purchasing agents and, thus, never actualized.

Relator Fry further provides five examples where specific patients were implanted with upgraded IMDs under warranty, but because hospital personnel were deprived access to the warranties, those hospitals paid full price for the upgrades, the costs ultimately being passed on to the federal government through Medicare and Medicaid reimbursement. n3 For instance, the Second Amended Complaint alleges that Patient A was upgraded from a single-chamber Guidant pacemaker to a dual chamber pacemaker on December 3, 1998. Although, under the warranty terms, the $ 6,000 price for the new dual chamber pacemakers should have been reduced [*7] by the original price of the older, single-chamber device -- $ 3,000 -- resulting in an overall price of $ 3,000 for the new pacemaker, no credit was given. The hospital was not provided with any documentation indicating that the device was being replaced, or that there was any entitlement to a warranty or any other credit. Instead, the hospital paid the full $ 6,000 price.

n3 In each case, Mr. Fry provides the specific dates for all procedures and the model and serial number for all Guidant devices at issue. Although Mr. Fry does not provide copies of the specific Medicare claims for each patient, records of specific claims have been provided by the United States for two of the patients and, as discussed below, this court may take judicial notice of those records for the purpose of this opinion.

Later, in 2005, Patient A was informed by a Guidant representative that he was entitled to another replacement, free of charge, by the same doctor and at the same hospital as the 1998 replacement. This second replacement [*8] procedure was performed on November 2, 2005. Although the patient had been told that the replacement would be free, and although a Guidant sales representative attended the procedure, no information concerning any warranty or recall credits was transmitted to the hospital. Instead, the Medicare records show that Guidant charged the hospital $ 11,875 for the cost of the newly implanted device. That cost was submitted to Medicare via its online system, and on November 21, 2005, Medicare paid out $ 5,554.35 on the claim.

Patient B underwent a similar upgrade procedure on January 12, 2005, to replace a device that had been implanted roughly two years earlier, on January 22, 2003. Under the "Cardiassure" program, the upgrade costs should have been offset by a credit for $ 5,000. However, no information concerning the credit was transmitted to the hospital, which, according to the complaint, included the entire price of the new device in its Medicare submission, yielding Guidant a net benefit of $ 5000.

Patient C underwent his upgrade procedure on March 22, 2005, to replace a device that had been implanted approximately one year earlier, on February 13, 2004. Under the "Cardiassure" program, [*9] the upgrade costs should have been offset by a credit of $ 5,000. However, the hospital was not provided with any information regarding the credit, and so, according to the complaint, the hospital paid the entire price to Guidant, and submitted the cost to Medicare. Guidant ultimately received the $ 5,000 benefit.

Patient D underwent his upgrade procedure on March 16, 2005, to replace a device that had been implanted on August 31, 2004. Under the "Cardiassure" program, the upgrade costs should have been offset by a credit of $ 5,000, but because the hospital was not provided with any information regarding that credit, no offset occurred. Instead, according to the complaint, the hospital paid the entire replacement cost and submitted that cost to Medicare, yielding a net benefit of $ 5,000 to Guidant.

Finally, Patient E underwent an upgrade procedure on April 6, 2005, to replace a device that had been implanted approximately two years earlier, on April 16, 2003. Under the "Cardiassure" program, the upgrade costs should have been offset by a credit of $ 5,000, but as with Patients A, B, C, and D, the hospital was not provided with any information regarding the credit. In fact, Mr. [*10] Fry alleges that the "implant form" indicated that the procedure was an "elective replacement," and therefore, even if a copy had been forwarded to the hospital, it would have contained no information as to any warranty credits. Instead, according to the complaint, the hospital paid the entire replacement cost and submitted the cost to Medicare. The Medicare records show that Patient E's claim was received by Medicare on April 14, 2005, and paid out on April 29, 2005, in the amount of $ 21,307.03. According to the complaint, that amount included reimbursement for the $ 5,000 credit.

On September 11, 2003, Mr. Fry filed this *qui tam* action n4 on behalf of the United States of America against Guidant Corporation, its predecessor Cardiac Pacemakers, Inc., and unknown entities and individuals, alleging that these defendants, in violation of the False Claims Act, *31 U.S.C. § 3729, et seq.*, knowingly engaged in a fraudulent systematic scheme to defraud the Medicare program by concealing the existence of rebates and/or credits for replacement IMDs, which, in turn; caused the U.S. Department of Health and Human Services to pay greater cost adjustment amounts [*11] throughout Tennessee and the United States. (Docket No. 1.) Pursuant to the statutory scheme set forth in the False Claims Act, the original complaint was filed under seal and served upon the United States, remaining under seal while the United States investigated the allegations therein and decided whether or not to intervene in the action. n5

n4 A *qui tam* action is one "brought by an informer, under a statute which establishes a penalty for the commission or omission of a certain act . . ., part of the penalty to go to any person who brings such action and the remainder to the state or some other institution." *United States ex rel. McKenzie v. Bellsouth Telcoms., 123 F.3d 935, 936 n. 1 (6th Cir. 1997)*(quoting Black's Law Dictionary 1251 (6th ed. 1990)).

n5 Pursuant to *§ 3730(b)(2) of the FCA*, a *qui tam* plaintiff must disclose to the government the information on which his or her claim is based. *31 U.S.C. § 3730(b)(2)*. If the government declines to intervene, the qui tam plaintiff may serve the complaint on the defendant and proceed with the action on his own. *31 U.S.C. § 3730(b)(4)(B)*. If the action is successful, private plaintiffs suing on behalf of the government receive a portion of the recovered funds as incentive to bring such claims. *31 U.S.C. § 3730(d)*.

[*12]

On July 22, 2004, Mr. Fry filed an Amended Complaint, adding Medtronic Inc. as a defendant and asserting new claims under the Federal Anti-Kickback Statute, *42 U.S.C. §§ 1320a-7b(b)*, and the Tennesee Medicaid False Claims Act, *Tenn. Code Ann. § 71-5-181 et seq.* against both Guidant and Medtronic, as well as claims under the California False Claims Act, *Cal. Gov't Code § 12650 et seq.*, and the Florida False Claims Act, Fl. Stat. *§ 68.081 et seq.*, solely against defendant Guidant. (Docket No. 14.)

On December 15, 2005, the court issued an order disclosing that the State of Tennessee had elected not to intervene and ordering the original complaint unsealed and served upon defendants. Thereafter, by Order dated January 17, 2006, the First Amended Complaint was unsealed and served. The United States and the states of Florida and California have as of yet declined to intervene. n6

n6 As discussed below, however, the United States have filed a motion giving the court notice of its pending reconsideration of participation in this case. (Docket No. 105).

[*13]

On February 1, 2006, defendant Guidant moved to dismiss the relator's FCA and related state law claims for failure to plead fraud with particularity under *Rules 9(b)* and *12(b)(6)* of the Federal Rules of Civil Procedure and failure to comply with the applicable statute of limitations. Guidant also moved to dismiss the relator's Anti-Kickback claim on standing grounds. (Docket No. 40.) On February 22, 2006, Medtronic filed a motion to dismiss, asserting that it was improperly joined in this action. On February 24, 2006, the relator moved for leave to file a second amended complaint. (Docket No. 78). On April 25, 2006, this court granted in part and denied in part both the defendants' and the relator's motions, dismissing with prejudice all of the relator's claims against Medtronic and his claims against Guidant under the Federal Anti-Kickback Statute, *42 U.S.C. §§ 1320a-7b(b)*, but granting the relator leave to amend to file a second amended complaint. (Docket No. 93.)

On May 4, 2006, the relator filed a second amended complaint, alleging (1) violation of the False Claims Act, *31 U.S.C. § 3729* [*14] , *et seq.*, (2) violation of the Tennesee Medicaid False Claims Act, *Tenn. Code Ann. § 71-5-181 et seq.*, (3) violation of the California False Claims Act, *Cal. Gov't Code § 12650 et seq.*, and (4) violation of the Florida False Claims Act, Fl. Stat. *§ 68.081 et seq.* (Docket No. 94.) Guidant moved to dismiss the second amended complaint on May 24, 2006. (Docket No. 95.)

**ANALYSIS**

**I. Motion to Dismiss Standard**

In deciding a motion to dismiss for failure to state a claim under *Rule 12(b)(6)*, the court will accept as true the facts as the plaintiff has pleaded them. *Inge v. Rock Fin. Corp., 281 F.3d 613, 619 (6th Cir. 2002)*;

*Performance Contracting, Inc. v. Seaboard Surety Co., 163 F.3d 366, 369 (6th Cir. 1998)*. "A complaint must contain either direct or inferential allegations with respect to all material elements necessary to sustain a recovery under some viable legal theory." *Performance Contracting, 163 F.3d at 369*.

The court will not dismiss a complaint for failure to state a claim unless "it appears beyond doubt that [*15] the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Myers v. United States, 636 F.2d 166, 168-69 (6th Cir. 1981)*(quoting *Conley v. Gibson, 355 U.S. 41, 45-46, 78 S. Ct. 99, 2 L. Ed. 2d 80 (1957))*. This narrow inquiry is based on whether "the claimant is entitled to offer evidence to support the claims," not whether the plaintiff can ultimately prove the facts alleged. *Swierkiewicz v. Sorema N.A., 534 U.S. 506, 511, 122 S. Ct. 992, 152 L. Ed. 2d 1 (2002)*(quoting *Scheuer v. Rhodes, 416 U.S. 232, 236, 94 S. Ct. 1683, 40 L. Ed. 2d 90 (1974))*. "Indeed it may appear on the face of the pleadings that recovery is very remote and unlikely but that is not the test." *Scheuer, 416 U.S. at 236*. Rather, challenges to the merits of a plaintiff's claim should be "dealt with through summary judgment under *Rule 56*." *Swierkiewicz, 534 U.S. at 514*.

*Rule 9(b) of the Federal Rules of Civil Procedure*, however, provides for a more stringent standard in fraud actions. Under that rule, in a complaint alleging fraud, "the circumstances constituting fraud . . . shall be stated with particularity." *Fed. R. Civ. P. 9(b)* [*16] . The Sixth Circuit has held that "the purpose undergirding the particularity requirement of *Rule 9(b)* is to provide a defendant fair notice of the substance of a plaintiff's claim in order that the defendant may prepare a responsive pleading." *Michaels Bldg. Co. v. Ameritrust Co., N.A., 848 F.2d 674, 679 (6th Cir. 1988)*; *see also Yuhasz v. Brush Wellman, Inc., 341 F.3d 559, 563 (6th Cir. 2003)*("The heightened pleading standard set forth in *Rule 9(b)* applies to complaints brought under the FCA.")

Generally, the Sixth Circuit advises that the *Rule 9(b)* requirement be construed "liberally, . . . requiring a plaintiff, at minimum, to allege the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." *Coffey v. Foamex L.P., 2 F.3d 157, 161-62 (6th Cir. 1993)*. When read in conjunction with *Rule 12(b)(6)*, *Rule 9(b)* requires a plaintiff to allege each element of a fraud claim in order to withstand a motion to dismiss. *See Craighead v. E.F. Hutton & Co., 899 F.2d 485, 491 (6th Cir. 1990)*. With [*17] that standard in mind, the court turns to an analysis of the relator's claims.

**II. Sufficiency of the Second Amended Complaint Under *Sanderson***

This court has addressed the sufficiency of the fraud allegations in the relator's Second Amended Complaint in its prior Memorandum of April 25, 2006. In that Memorandum, this court held that "the proposed Second Amended Complaint adequately describes defendant Guidant's allegedly fraudulent scheme to defraud the United Sates of Medicare and Medicaid funds so as to ensure that defendant Guidant has received notice of the charges against it." *2006 U.S. Dist. LEXIS 29862, No. 3:03-0842, 2006 WL 1102397, *8 (M.D. Tenn. Apr. 25, 2006)*. The defendant argues that the court should revisit that holding because, in an intervening decision -- *Sanderson v. HCA-The Healthcare Co., 447 F.3d 873, 877 (6th Cir. 2006)* -- the Sixth Circuit clarified the requirements for pleading fraud in *qui tam* actions. However, the court finds that *Sanderson* did not constitute an intervening change of law, but rather upheld the preexisting law that this court has already applied. Therefore, under the law of the case doctrine, the court should not [*18] readdress the issue. Further, the court holds that, under the framework announced in *Sanderson*, the relater has adequately pled a cause of action under the FCA.

**A. Law of the Case**

The law of the case doctrine posits that, "when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." *EEOC v. United Ass'n of Journeymen & Apprentices of the Plumbing & Pipefitting Indus. of the United States & Canada, Local 120, 235 F.3d 244, 249 (6th Cir. 2000)*(quoting *Arizona v. California, 460 U.S. 605, 618, 103 S. Ct. 1382, 75 L. Ed. 2d 318 (1983))*. The doctrine operates such that "findings made at one point in the litigation become the law of the case for subsequent stages of that same litigation," *Rouse v. DaimlerChrysler Corp., 300 F.3d 711, 715 (6th Cir. 2002)*, and therefore, "[i]t is within the sole discretion of a court" to determine whether those findings should be reconsidered. *United States v. Todd, 920 F.2d 399, 403 (6th Cir. 1990)*. The

Supreme Court has ruled that, "[u]nder law of the case doctrine, as now most commonly understood, it is not improper for [*19] a court to depart from a prior holding if convinced that it is clearly erroneous and would work a manifest injustice," and instead, "[l]aw of the case directs a court's discretion, it does not limit the tribunal's power." *Arizona v. California, 460 U.S. at 618*.

As the defendant points out, the Sixth Circuit has held that an exception to the law of the case doctrine can arise where there is "a subsequent contrary view of the law by the controlling authority." *U.S. v. Campbell, 168 F.3d 263, 269 (6th Cir. 1999)*(quoting *U.S. v. Moored, 38 F.3d 1419,1421 (6th Cir. 1994)*; *see also EEOC v. K-Mart Corp., 796 F.2d 139, 146 (6th Cir. 1986)*(holding that a prior opinion could not control where the Supreme Court had expressed the opposite view in an intervening case). The defendant argues that *Sanderson, 447 F.3d at 877,* although it did not overturn precedent, requires that this court revisit its prior holding because it "clarified existing law by setting forth very specific pleading requirements." (Docket No. 104 at p. 3.) However, the court finds that, although the Sixth Circuit did "clarify existing law" [*20] in *Sanderson,* it did not do so in a way inconsistent with this court's prior holding and, therefore, the law of the case doctrine applies.

The Sixth Circuit's decision in *Campbell, 168 F.3d at 269,* which the defendant cites in support of its argument that this court must make an exception to the law of the case doctrine, actually supports the opposite position. In *Campbell,* the court addressed whether a change in the sentencing law obliged the district court to consider the new law on remand. *Id.* The court held that, although "a subsequent contrary view of the law by the controlling authority" was an exception to the law of the case doctrine, that exception did not apply because the amendment "did not substantively alter the guideline, but merely clarified or explained it." *Id.*

As in *Campbell,* the court is presented with an intervening decision by a controlling authority that does not actually present a "contrary view of the law" but instead "merely clarifie[s]" existing law. In the intervening decision at issue, *Sanderson, 447 F.3d at 877,* the Sixth Circuit upheld the district court's finding that the plaintiff had failed to [*21] allege an FCA claim with particularity as required by *Rule 9(b)*. The plaintiff's complaint had merely described an accounting method said to be "prohibited" and asserted that any claims made to the government under that method must necessarily violate the FCA, without actually identifying "any specific claims that were submitted to the United States or identify[ing] the dates on which those claims were presented to the government," relying instead on "conclusory allegations of fraudulent billing." *Id. at 877-78* (quoting *United States ex rel. Clausen v. Laboratory Corp. of America, Inc., 290 F.3d 1301, 1310 (11th Cir. 2002))*. The court in *Sanderson,* far from presenting a "contrary view of law" to its prior decisions, specifically held that "the district court's *Rule 9(b)* determination was fully in conformity with existing Sixth Circuit precedent, notably our recent False Calims Act decision in *Yuhasz,* as reaffirmed in *United States ex rel. Bledsoe v. Cmty. Health Sys., 342 F.3d 634 (6th Cir. 2003)*." *Id. at 878*. Both *Yuhasz* and *Bledsoe* were cited by this court in its decision holding that the relator [*22] in this case "alleges sufficient facts from which a reasonable juror could infer that the defendants' fraudulent course of conduct in concealing warranties and upgrade credits was causally connected to the Medicare claims submitted by participating hospitals." *2006 U.S. Dist. LEXIS 29862, No. 3:03-0842, 2006 WL 1102397, *8 n.10, (M.D. Tenn. Apr. 25, 2006)*. In short, there was no change in law.

In noting the factual similarity between its own set of facts and those presented in the Eleventh Circuit case, *United States ex rel. Clausen v. Laboratory Corp. of America, Inc., 290 F.3d 1301, 1310 (11th Cir. 2002),* the *Sanderson* court did, for the first time, adopt the Eleventh Circuit's language that:

> [I]n *qui tam* actions, the heightened pleading requirements of *Rule 9(b)* are met by a complaint that sets out: (1) precisely what statements were made in what documents or oral representations or what omissions were made, and (2) the time and place of each such statement and the presons responsible for making (or in the case of omissions, not making) same, and (3) the content of such statements and the manner in which they misled the [government], and (4) what the defendants [*23] obtained as a consequence of the fraud. *447 F.3d at 877* (quoting *Clausen, 290 F.3d at 1310*).

However, as the court in *Sanderson* noted itself, the above language does not contradict, but rather underpins the longstanding rule in this circuit that, in FCA cases, "the failure to identify specific parties, contracts, or fraudulent acts require[s] dismissal." *Id. at 879* (quoting *Yuhasz, 341 F.3d at 564*). That was the rule applied by this court when it held that Mr. Fry had satisfied the *Rule 9(b)* requirements in his Second Amended Complaint and, as the law of the case, the court declines to revisit that holding.

Moreover, as this court previously held, an analysis of the record reveals that Mr. Fry has well met the *Rule 9(b)* pleading requirements for his FCA cause of action. Mr Fry, aside from alleging with particularity the overall scheme by which the defendant sought to preclude the hospitals from utilizing warranty credits, has in addition set forth five specific examples of upgrade procedures where hospitals were kept ignorant of those credits, and the cost was ultimately passed on to the federal government through Medicare. [*24] For each of those examples, Mr. Fry has provided the specific date of the procedure in question and the model and serial number of the Guidant devices that were implanted and replaced. In so doing, he met the specificity requirement of *Rule 9(b)*. n7

n7 In addition, as discussed below, for two of the relator's examples -- Patient A and Patient E -- the United States has since filed Medicare records showing that, for both patients, the hospital submitted the entire cost of the device at issue for compensation, without inclusion of any warranty credits.

**B. The Medicare Records**

Although the court declines to revisit its prior holding on the sufficiency of the relator's Second Amended Complaint, which was made without regard to the Medicare records filed under seal by the United States, it must address the defendant's motion to strike those records, as well as its motion to strike the United States' motion of its pending reconsideration of intervention in this case. (Docket No. 108; 116.) The court finds the [*25] defendant's arguments, in support of both motions -- that the filings are "out of time" and present due process concerns -- unavailing and will deny both motions. n8

n8 The defendant has also moved to strike the relator's omnibus brief in response to the various pending motions, arguing that the brief is irrelevant and untimely. (Docket No. 119.) The court is not convinced that the omnibus brief is irrelevant, although it is perhaps duplicative of earlier filings. In addition, although the relator did not seek leave to file the omnibus brief, the court is convinced by the plaintiff's response that the omnibus brief was not untimely under Local Rule 7.01(b). Accordingly, the court will deny the defendant's motion to strike the omnibus brief. However, the court notes that it found the brief to be largely cumulative.

As the United States points out, it remains the real party in interest in this case and may elect to intervene on a showing of good cause pursuant to *31 U.S.C. § 3730(b)(3)* [*26] and *(c)(3)*. Whether or not the United States is "out of time" may be addressed at such time as it actually chooses to intervene in this case; for now its intervention can neither be "out of time" or "on time" because it has not taken place and may never take place. Of course, the fact that the United States is considering intervening in this case is not itself relevant to the sufficiency of the relator's complaint; however, inasmuch as it may prove relevant to future motions, and the defendant has not provided the court with a compelling reason to strike the motions, the court will decline to strike the United States' motions.

Citing just one case in its favor, the defendant also argues that the United States' notice of pending reconsideration and its documents filed under seal must be stricken for violation of procedural due process. It is telling that the one case the defendant cites -- *Kelly v. Metropolitan County Bd. of Educ., 372 F. Supp. 540, 560 (M.D. Tenn. 1973)* -- has little to do with the situation at hand. In *Kelly*, individual members of the Nashville Board of Education were sued for failure to follow their own governing regulations in enacting and [*27] enforcing a busing program required by the Supreme Court's *Swann* decision. *Id. at 541-43*. The defendants were found to have actively thwarted the regulatory system which they were charged with enforcing and, on that basis, to have violated the plaintiff's right to procedural due process. *Id. at 560*. *Kelly* has little or nothing to say regarding the defendant's argument that the court must strike evidence from the record because it was provided by the United States, without the United States having moved to intervene. The defendant has pointed this court to no provision of the FCA -- and this court has found none -- stating that the United States may not give the court notice that it is reconsidering intervening or provide the court with administrative records that are pertinent to the case at hand. Neither the United States' notice of pending reconsideration nor the Medicare documents filed under seal implicate the defendant's due process rights, procedural or otherwise.

As stated above, the court declines to address its prior decision, it having become the law of the case in this litigation and, therefore, does not base its present decision [*28] on the records provided by the United States. However, it is important to note that, as a long-standing practice, courts have taken judicial notice of information, such as government records, not provided by either party in determining motions to dismiss. *See, e.g., In re Cardinal Health Inc. Securities Litigations, 426 F. Supp. 2d 688, 712 (S.D. Ohio 2006)*("[A] court may consider any matters of which a court may take judicial notice without converting a party's motion to dismiss into a motion for summary judgment."); *In re Keithley Instruments, Inc. Securities Litigation, 268 F. Supp. 2d 887, 893 (N.D. Ohio 2002)*("[T]he Court may consider public records and matters of which a court may take judicial notice without converting the motion to dismiss into a motion for summary judgment.")(citing *Weiner v. Klais & Co., 108 F.3d 86, 89 (6th Cir. 1997))*.

The practice of taking judicial notice is governed by *Rule 201 of the Federal Rules of Evidence.* Under *Rule 201,* a court has discretion to take judicial notice, whether requested or not, of any fact "not subject to reasonable dispute, in that it is [*29] either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." *Fed. R. Evid. 201 (b), (c)*. Judicial notice has often been afforded in situations such as this one.

For instance, in *Denius v. Dunlap, 330 F.3d 919, 926-27 (7th Cir. 2003),* the Seventh Circuit held that the trial court had abused its discretion in refusing to take judicial notice of medical records contained on the National Personnel Record Center's website. In so holding, the court reasoned that "[t]he information on the website was not duplicative; . . . rather, it would have provided essential corroboration" of the plaintiff's testimony at trial. *Id. at 926*. Further, the medical records were particularly suited for judicial notice because they were "not subject to reasonable dispute." *Id.* Finally, after exercising its own authority to take judicial notice of the facts contained on the website, the Seventh Circuit noted that "[t]he defendants have simply caused additional judicial work by contesting a factual [*30] issue that, according to information readily available in the public domain, cannot be reasonably disputed." *Id. at 927*; *see also Toth v. Grand Trunk Railroad, 306 F.3d 335 (6th Cir. 2002)*(holding that federal regulations concerning railroads were properly subject to judicial notice); *Disabled Rights Action Committee v. Las Vegas Events, Inc., 375 F.3d 861, 865 n.1 (9th Cir. 2004)*("[W]e may take judicial notice of the records of state agencies and other undisputed matters of public record."); *Stutzka v. McCarville, 420 F.3d 757, 761 n.2 (8th Cir. 2005)*("[W]e may take judicial notice of judicial opinions and public records.")(citations omitted).

Accordingly, the court notes that it may take judicial notice of the Medicare documents provided by the United States for the purpose of this motion. Those documents, filed under seal, are print-outs of electronic submissions for reimbursement made to Medicare concerning the implant procedures performed on Patients A and E, concerning which the relator has already provided specific information in his Second Amended Complaint. The documents corroborate the plaintiff's allegation [*31] that, for both Patient A and Patient E, the hospital submitted the entire cost of the Guidant device for reimbursement and did not reduce the price in accordance with Guidant's warranty credits. Because the documents constitute records kept by a state agency, they are "not subject to reasonable dispute," *Denius v. Dunlap, 330 F.3d at 926*, and, therefore, under *Rule 901*, they are proper for judicial notice. The court does not rely on the records only in so much as it declines to revisit its prior holding, as the law of the case in this action.

**III. Sufficiency of the Underlying Fraudulent Conduct**

In addition, the defendant argues that the Second Amended Complaint must be dismissed because the defendant's alleged conduct in this case cannot be considered fraudulent as a matter of law. Inasmuch as the court addressed the merits of the relator's fraud allegations previously, in its April 26, 2005 ruling, it will, again, decline to revisit that issue in this opinion under the law of the case doctrine. However, the court will note that the defendant appears to misunderstand the allegations that the relator has brought against it. In order to state a claim under [*32] the FCA in this case, the relator must plead that the defendant caused a false claim to be presented through false or fraudulent conduct. *31 U.S.C. § 3729(a)(1)*. As this court held on April 26, 2005, the relator has met those pleading requirements.

**A. False or Fraudulent Conduct**

The relator has not brought a "fraud by omission" cause of action, and his case does not rely on any "legal obligation requiring Guidant to (i) offer warranty credits in the first place; (ii) ensure that hospital personnel responsible for submitting reimbursement claims receive the warranties; or (iii) ensure that hospitals use and properly claim the warranty credits when seeking Medicare or Medicaid reimbursement." (Docket No. 96 at p. 10-11.) Rather, the relator alleges that the defendant engaged in affirmative, fraudulent conduct designed to keep the hospital personnel actually responsible for paying Guidant and for submitting for Medicare and Medicaid reimbursement from knowing about the warranty credits that Guidant claimed to be offering. *See United States v. Birnie, 193 Fed. Appx. 528, 2006 U.S. App. LEXIS 21713, No. 04-2070, 04-2401, 2006 WL 2456945 (6th Cir. Aug. 24, 2006)*(unreported)("A misrepresentation [*33] can be made through omissions or through circumstances "reasonably calculated to deceive persons of ordinary prudence and comprehension. . . Deception is not necessarily confined to a direct misstatement of fact.")(citing *United States v. Hathaway, 798 F.2d 902, 908 (6th Cir. 1986)*; *United States v. Lichota, 351 F.2d 81, 91 (6th Cir. 1965))*.

Allegations suffice under the FCA "if they state that defendant made a record or statement known to be false or fraudulent in order to get a false claim paid." *United States ex rel. Riley v. St. Luke's Episcopal Hospital, 355 F.3d 370, 378 (5th Cir. 2004)*. "False," in this usage, means "deceitful" or "tending to mislead," and a "false claim" is one "grounded in fraud which might result in a financial loss to the Government." *Peterson v. Weinberger, 508 F.2d 45, 52 (5th Cir. 1975)*. The False Claims Act "reaches beyond 'claims' which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money." *Id; see also United States v. Neifert-White Co., 390 U.S. 228, 232, 88 S. Ct. 959, 19 L. Ed. 2d 1061 (1968)*(holding that the FCA is "intended to reach all types [*34] of fraud, without qualification, that might result in financial loss to the Government").

For instance, in *U.S. ex rel. Augustine v. Century Health Services, Inc., 289 F.3d 409, 413-415 (6th Cir. 2002)*, the Sixth Circuit held that an FCA claim had been adequately pled where the defendant submitted cost reports to Medicare regarding an Employee Stock Ownership Plan ("ESOP") that were not false at the time they were submitted but, because the money was transferred out of the ESOP shortly after the cost reports were sent, were rendered misleading shortly thereafter. Reasoning that "the maxim that [m]en must turn square corners when they deal with the Government," *id. at 413* (citing *United States ex rel. Compton v. Midwest Specialties, Inc., 142 F.3d 296, 302 (6th Cir. 1998)*, the court held that the cost reports could be considered fraudulent solely on the basis that they had each included a certification stating that, "to the best of my knowledge and belief, [the cost report] is a true, correct, and complete report prepared from the books and records of the provider in accordance with applicable instructions, except as noted." [*35] *Id. at 414*. The Sixth Circuit agreed with the trial court that, "[b]y making this certification, Defendants represented that they would continue to comply with Medicare regulations . . . or notify the [government]" if the ESOP expenses were withdrawn. *Id. at 414-415*. Therefore, although the cost reports had not been expressly false at the time they were submitted, the court held that "liability can attach if the claimant violates its continuing duty to comply with the regulations on which payment is conditioned." *Id. at 415*.

Here, as the court previously held, the relator has alleged sufficient "false or fraudulent conduct." The relator has alleged that it was the defendant's policy to destroy warranties by placing them in trash cans in order to keep hospital personnel from actualizing the warranty credits. As in *Century Health Services*, the defendant allegedly made representations regarding the warranty credits that, although they were not false at the time they were made, would be rendered false by its alleged subsequent conduct in preventing the warranty credits from being used. For instance, the Second Amended Complaint alleges that Guidant salesmen used the [*36] warranty credits as a sales incentive when convincing doctors to demand that hospitals use Guidant IMDs. Those representations would be rendered false by a subsequent plan to conceal the warranties from the hospital personnel who were actually responsible for utilizing the credits.

In addition, as discussed further below, the Second Amended Complaint alleges that, for each request to Medicare and Medicaid for reimbursement, the defendant's customers signed a certification stating: "I am familiar with the laws and regulations regarding the provisions of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations." (Docket No. 94 at P 92.) Further, the Second Amended Complaint sets forth language from the Medicare Intermediary Manual requiring that reimbursement may not be had for medical devices where a warranty reimbursement from the manufacturer could have been obtained, but was not. For instance, the Second Amended Complaint alleges that § 2103 ("Prudent Buyer") provides the following example:

> Provider B purchases cardiac pacemakers or their components for use in replacing malfunctioning or obsolete [*37] equipment, without asking the supplier/manufacturer for full or partial credits or payments available under the terms of the warranty covering the replaced equipment. The credits or payments that could have been obtained must be reflected as a reduction of the cost of the equipment supplied. (*Id.* at P 99.)

As in *Century Health Services*, the failure of the hospitals to follow the Prudent Buyer regulation, while certifying that "the services identified in this cost report were provided in compliance" with the applicable laws and regulations, could demonstrate that the claims at issue were false or fraudulent. If it could be proven that the defendant caused those false claims to be presented, as discussed below, then the defendant could be held liable under the FCA.

**B. Presents or Causes to be Presented**

Under the False Claims Act, a defendant who "knowingly presents, or causes to be presented . . . a false or fraudulent claim for payment or approval" can be held liable. *31 U.S.C. § 3729(a)(1)*. In accordance with the language "knowingly presents, *or causes to be presented" 31 U.S.C. § 3729(a)(1)*(emphasis added), it [*38] has long been "settled that the [FCA] . . . gives the United States a cause of action against a subcontractor who causes a prime contractor to submit a false claim to the Government." *United States v. Bornstein, 423 U.S. 303, 309, 96 S. Ct. 523, 46 L. Ed. 2d 514 (1976)*; *see also Riley v. St. Luke's Episcopal Hospital, 355 F.3d at 378* ("The FCA applies to anyone who knowingly assists in causing the government to pay claims grounded in fraud without regard to whether that person has direct contractual relations with the government. . . . Thus, a person need not be the one who actually submitted the claim forms in order to be liable.")(internal quotations and citations omitted). Here, the plaintiff does not allege that the defendant itself presented a false or fraudulent claim for payment or approval, but that the defendant caused such a claim to be presented by hospital personnel.

False Claims Act cases involving fraudulent schemes to defraud Medicare and Medicaid are not strangers to the federal courts. In *United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 243-45 (3d Cir. 2004)*, the Third Circuit addressed whether a *qui tam* relater had stated a cause [*39] of action under the FCA by alleging that the defendant, Zimmer -- a manufacturer, seller, and distributer of orthopedic implants -- had created "a marketing scheme that it knew would, if successful, result in the submission . . . of compliance certifications required by Medicare that Zimmer knew would be false." Under the marketing scheme in *Zimmer*, the defendant provided rewards to its customers "in cash or cash equivalents" for purchasing its orthopedic implants, without reporting the rewards on their cost reports to Medicare for reimbursement. *Id. at 237*. In reversing the district court's dismissal of the action, the Third Circuit held that the cost reports were sufficiently "false" for failure to disclose the rewards the customers had received from Zimmer and that, by creating the cash reward plan, Zimmer had knowingly caused the false cost reports to be submitted. *Id. at 243-45*.

Unlike the defendant in *Zimmer*, in this case, the defendant is not alleged to have acted in complicity with its customers in presenting fraudulent claims but, rather, to have caused its customers to have presented fraudulent claims unwittingly. Nevertheless, the [*40] *Zimmer* decision is instructive. As in *Zimmer*, the defendant's alleged scheme in this case caused its customers to submit requests for reimbursement with false compliance certificates. As discussed above, the relator has alleged specific Medicare regulations stating that hospitals cannot receive reimbursement for medical devices under warranty above "the amount it would have had to pay if it had pursued the warranty." (Docket No. 94 at P 98.) Additionally, the relator has alleged that hospital personnel signed certifications with each reimbursement request, certifying that the hospitals had complied with the governing Medicare and Medicaid regulations. However, under the relator's allegations, the hospitals failed to comply with those regulations, unwittingly, because they requested reimbursement for the full cost of Guidant's devices in almost every instance. As in *Zimmer*, the defendant in this case could be held liable under the FCA if it can be shown that it caused the hospitals' failure to comply with those regulations by concealing the existence of warranty credits.

**IV. The Relator's Motion to Authorize Disclosure**

Finally, the court must address the relator's [*41] motion seeking an order to authorize disclosure to its counsel and other necessary parties of certain information relevant to this case that is protected by the Health Insurance Portability and Accountability Act ("HIPPA"), to which the defendant has not responded. The relator requests social security numbers and health information "in order to obtain copies of the false claims which [the relator alleges] Guidant caused hospitals to submit to the government, to prove the full extent and detail of the fraud perpetrated on the United States government, and to calculate damages." (Docket No. 106 at p. 2.)

The relator seeks this order pursuant to *45 CFR § 164.512(e)(1)*, which provides that:

> A covered entity may disclose protected health information in the course of any judicial or administrative proceeding:
>
> (1) In response to an order of a court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order.

In its proposed Order, the relator seeks identifying information from each patient who has received a Guidant IMD, or from whom a Guidant IMD was explanted, [*42] or who received an IMD "lead" upgrade from September 11, 1997, to date. In addition, the relator seeks model and serial numbers for the IMDs in question; purchase orders, invoices, cost reports; and other information relating to the individual IMD procedures and the payment for those procedures.

Because the requested information is related to the relator's claims and may be necessary for the relator to present his case at trial, the court will grant the relator's unopposed motion. Accordingly, the court will issue a separate order authorizing disclosure of the requested information.

**CONCLUSION**

For the reasons stated herein, the defendant's Motion to Dismiss will be denied, the defendant's Motion to Strike the United States' Notice of Pending Reconsideration will be denied, the Defendant's Motion to Strike the United States' Documents Filed Under Seal will be denied, and the defendant's Motion to Strike the Relator's Omnibus Brief will be denied. The relator's Motion to Authorize Disclosure will be granted.

An appropriate order will enter.

ALETA A. TRAUGER

United States District Judge

**ORDER**

For the reasons expressed in the accompanying Memorandum, the Motion [*43] to Dismiss filed by defendant Guidant Corporation (Docket No. 96), will be **DENIED,** the Motion to Authorize Disclosure filed by the relator (Docket No. 106), will be **GRANTED,** the Motion to Strike the United States' Notice of Pending Reconsideration filed by defendant Guidant Corporation (Docket No. 108), will be **DENIED,** the Motion to Strike Documents Filed Under Seal filed by defendant Guidant Corporation (Docket No. 116), will be **DENIED,** and the Motion to Strike the Relator's Omnibus Brief filed by defendant Guidant Corporation (Docket No. 119), will be **DENIED.**

It is so ordered.

Enter this 13th day of September 2006.